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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

14

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No. 09/804,060	Applicant(s) MOCKEL ET AL.	
	Examiner Kathleen M Kerr	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 10-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9 and 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (Paper No. 13, mailed on September 30, 2002), Applicants filed an amendment and response received on March 6, 2003 (Paper No. 14). Said amendment amended Claims 1-5 and 7-9 and added new Claims 20-23. Claims 1-23 are pending in the instant Office action.

Election

2. As previously noted, Applicant's elected without traverse Group I, Claims 1-5 and 7-9. New Claims 20-23 are drawn to the subject matter of Group I. Claims 1-23 are pending in the instant Office action. Claims 6 and 10-19 are withdrawn from further consideration as non-elected inventions. Claims 1-5, 7-9, and 20-23 will be examined herein.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the foreign application 100 42 740.5 filed in Germany on August 31, 2000. The instant application is also granted the benefit of priority for the foreign application 101 08 463.3 filed in Germany on February 22, 2001. No foreign translation has been filed.

Drawings

4. As previously noted, the drawings have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

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Withdrawn - Objections to the Specification

5. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicant's amendment to the title.

6. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicants' amendment to the specification.

7. Previous objection to the specification for informalities is withdrawn by virtue of Applicant's amendment.

8. Previous objection to the specification for containing German with English in brackets is withdrawn by virtue of Applicants' amendment.

9. Previous objection to the specification for containing "[sic]" due to the translation is withdrawn by virtue of Applicants' amendment.

Withdrawn - Objections to the Claims

10. Previous objection to Claims 1 and 8 for containing the abbreviation "[sic]" is withdrawn by virtue of Applicants' amendment.

11. Previous objection to Claim 5 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicant's amendment.

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12. Previous objection to Claim 8 for containing German with English in brackets is withdrawn by virtue of Applicant's amendment.

13. Previous objection to Claim 8 for not having the proper form is withdrawn by virtue of Applicants' amendment.

14. Previous objection to Claims 4, 7 and 9 for depending from rejected claims is withdrawn by virtue of Applicants' amendment and/or new rejections of the parent claims.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

15. Previous rejection of Claims 1-3 and 5 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "from coryneform bacteria" is withdrawn by virtue of Applicants' amendment.

16. Previous rejection of Claims 1-3 and 5 under 35 U.S.C. § 112, second paragraph, as being indefinite for Item c) in Claim 1 is withdrawn by virtue of Applicants' amendment deleting this item.

17. Previous rejection of Claims 1-3 and 5 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "preferably" is withdrawn by virtue of Applicants' amendment.

18. Previous rejection of Claims 1-3 and 5 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "activity of the sensor kinase CitA" is withdrawn by virtue of Applicants' amendment deleting this phrase.

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19. Previous rejection of Claim 5 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “within the range of degeneration of the genetic code”, the phrase “and optionally”, and the phrase “sense mutations of neutral function in (i)” is withdrawn by virtue of Applicant’s amendment.

20. Previous rejection of Claim 8 under 35 U.S.C. § 112, second paragraph, as being indefinite for the indentations titled “8.1”, “8.2”, etc. is withdrawn by virtue of Applicant’s amendment.

21. Previous rejection of Claim 5 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants’ amendment to Claim 5 so as to be drawn to an exact structure with inherent function.

22. Previous rejection of Claims 1-3 and 5 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for polynucleotides with at least, for example, 90% sequence identity to a polynucleotide that encodes SEQ ID NO:2, does not reasonably provide enablement for polynucleotides with such low sequence identity, such as the 70% identity claimed, is withdrawn by virtue of Applicants’ amendment.

Maintained - Claim Rejections - 35 U.S.C. § 112

23. Previous rejection of Claims 1-3 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants’ arguments have been fully considered but are not deemed persuasive. Applicants’ argue that the amendment to Claim 1 has obviated the instant rejection; this is not the case. Claim 1 is now drawn to a polynucleotide with variable structure

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(90-95% identical) and no function (Applicants' deleted the unclear "sensor kinase" functionality). A portion of the previous rejection is reiterated for convenience.

"The instant specification discloses polynucleotides related to SEQ ID NO:1 and related to polynucleotides encoding SEQ ID NO:2. Applicants have fully described the genus relating to said SEQ ID NOs with both sequence identity limitations and functional limitations (i.e., encoding the *citA* gene product, a sensor kinase). However, the genus of the instant claims also contains polynucleotides within the sequence identity limitations, but having different function. Applicants have not fully described a genus that has sequence identity limitations in the absence of functional limitations so that one of skill in the art would be able to predict the other members of the claimed genus. The Examiner suggests adding clear function limitations to the claims wherein the polynucleotide claimed must encode a polypeptide having sensor kinase activity."

By virtue of Applicants' amendment reciting "native to coryneform bacteria", an additional issue of written description must be considered with respect to the instant claims. While the specification adequately describes the genus of polynucleotides within the % identity range claimed, the specification does not adequately describe the *subgenus* of polynucleotides within the % identity range claimed that are *native to coryneform*. No particular description of coryneform DNA is found in the specification. While clearly such sequences are enabled by virtue of the skill in the art of producing DNA libraries and screening them, the structures of such sequences – in the absence of those not from coryneform – has not been distinguished in the specification as originally filed. To obviate *this portion* of the rejection, the Examiner suggests deleting the phrase "native to coryneform bacteria".

24. Previous rejection of Claim 8 under 35 U.S.C. § 112, first paragraph, enabling deposit, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants' argue that the declaration under the Budapest Treaty filed by Applicants'

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representative obviated the instant rejection. This is not the case. To overcome the instant rejection by enabling the deposit of DSM 13998, Applicants must amend the specification to include (4) the name and **full address** of the depository (37 C.F.R. § 1.801 - 1.809) as previously noted.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

25. Previous rejection of Claims 1-2 and 4 under 35 U.S.C. § 102(b) as being anticipated by Mizuki *et al.* is withdrawn by virtue of Applicants' amendment.

NEW OBJECTIONS/REJECTIONS

Objections to the Specification

26. The specification is objected to for lacking consistency concerning SEQ ID NO:3. On page 22, a 480 base pair internal fragment of SEQ ID NO:1 is noted as SEQ ID NO:3; however, SEQ ID NO:3 has 481 base pairs. Correction of this discrepancy is required.

Claim Objections

27. Claim 5 is objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of Claim 4. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See M.P.E.P. § 706.03(k). The Examiner notes that SEQ ID NO:1 is described as DNA in the sequence listing.

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28. Claim 22 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Neither the specification nor the art describe any difference between a short polynucleotide, such as a 30-mer of SEQ ID NO:1, and a probe or primer. Thus, the limitations of being a probe or primer does not effectively further limit the subject matter of the parent claim.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

29. Claims 8-9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A fragment of 480 base pairs is claimed; however, SEQ ID NO:3 is 481 base pairs. Clarification of this discrepancy is required.

30. Claim 21 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if the fragment limitation related to only SEQ ID NO:1 or also to its complement. Clarification is required.

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Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

31. Claims 1-5, 7, and 20-23 are rejected under 35 U.S.C. § 102(e) as being anticipated by Nakagawa *et al.* (USPAP 2002/0197605). The instant claims are drawn to SEQ ID NO:1 or the complement thereof.

Nakagawa *et al.* teach a polynucleotide (sequence 77) that is 100% identical to SEQ ID NO:1 in the instant application (see previously attached alignment from EP 1108790) as well as fragments, complements, and vectors thereof.

The Examiner notes that USPAP 2002/0197605 is the U.S. equivalent of EP 1108790 previously noted as relevant prior art. The filing date of the USPAP is December 18, 2000 that pre-dates the filing date of the instant application, but not foreign priority document DE 100 42 740.5 filed on August 31, 2000. If this DE document discloses the invention of the instant claims, the Examiner suggests filing a translation of said document so that priority back to this filing date might be attributed and the rejection withdrawn.

Summary of Pending Issues

32. The following is a summary of the issues pending in the instant application:

- a) The specification stands objected to for lacking consistency concerning SEQ ID NO:3.
- b) Claim 5 stands objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of Claim 4.
- c) Claim 22 stands objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.
- d) Claims 8-9 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for a fragment of 480 base pairs.
- e) Claim 21 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the fragment limitation as related to the complement.
- f) Claims 1-3 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
- g) Claim 8 stands rejected under 35 U.S.C. § 112, first paragraph, enabling deposit.
- h) Claims 1-5, 7, and 20-23 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Nakagawa *et al.* (USPAP 2002/0197605).

Conclusion

33. Claims 1-5, 7-9, and 20-23 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

The instant Office action is **NON-FINAL** based on the new rejection under 35 U.S.C. § 102(e) set forth herein.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



KMK

May 23, 2003